

REMARKS

Please reconsider the application in view of the foregoing amendments and the following remarks. Applicants thank the Examiner for indicating that claim 16 is allowed and that claim 18 contains allowable subject matter. Applicants also thank the Examiner for the courtesies extended during the informal Examiner Interview of August 5, 2004.

Examiner Interview

An informal Examiner Interview was conducted on August 5, 2004. During the interview, Applicants noted that the Fischell reference cited in the outstanding office action was previously considered during the prosecution of a related application that issued as U.S. Patent No. 6,554,809.

The Examiner suggested amendment of the independent claims to specify that the cutting surface is "sharp." Furthermore, the Examiner indicated that specifying that the cutting surface extended along a bottom surface of the needle would also be helpful. The claims have been amended accordingly.

Disposition of Claims

Claims 1-21 are pending in this application. Claims 1, 8, 16, and 17 are independent. The remaining claims depend, directly or indirectly, from these claims.

Claim Amendments

Claim 18 is amended in this response to incorporate the limitations of the independent claim from which it depends. Accordingly, this claim is now in independent

claim format. No new matter has been added by way of this amendment, support for which may be found at least in the original dependent claim.

Independent claims 1, 8, and 17 are amended in this response to clarify that the cutting surface is sharp, and extends along a portion of the bottom surface of the needle. No new matter has been added by way of these amendments, support for which may be found at least in Figs. 5 and 5A – 5C of the application.

Applicants believe these amendments make the claims allowable or simplify matters on appeal. Accordingly, entry of these amendments is respectfully requested.

Objections

Claim 18 is objected to as being dependent upon a rejected base claim. Claim 18 is amended in this response to incorporate the limitations of the independent claim from which it depends. Accordingly, this objection is now moot.

Rejection under 35 U.S.C § 102

Claims 1-6, 8-10, 11-15, 17, 20, and 21 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,141,365, issued to Fischell et al. (“Fischell”). Independent claims 1, 8, and 17 are amended in this reply to clarify that the cutting surface extends along a portion of the bottom surface of the distal end of the needle. To the extent this rejection may apply to the amended claims, it is respectfully traversed.

Independent claims 1, 8, 16, and 17 relate to a needle comprising a hollow shaft having opposed distal and proximal ends. At the top of the distal end is the opening of a lumen and at the bottom of the distal end is a sharpened cutting surface that extends along

a portion of the bottom surface. Such an embodiment advantageously facilitates insertion into an interspinal space, while decreasing the likelihood of trauma to the spinal fibers as the needle is inserted.

In contrast to such an embodiment, Fischell discloses a tissue stimulation apparatus having a sharpened, *oblique point* 14 (Col. 3, ll. 56-57). The Fischell apparatus may also have a point 14 that is upwardly curved (Col. 5, ll. 33-34). The point 14 of the apparatus according to Fischell, similar to that of a typical prior art medical needle, is designed to pierce tissue, in contrast to the separating/cutting design of the instant invention as shown in Figs. 1 and 5.

Although Fig. 1a of Fitchell includes a reference number (14) that points to a bottom surface of the tip of the needle, Applicants assert that this is done simply to indicate the point of the needle, and not to specify a bottom surface. Throughout the specification, Fischell refers only to a **point** and makes no reference at all to cutting, or a cutting surface.

Furthermore, the Fischell device is designed to penetrate in an upwardly direction as shown in Figs. 2, 6, 7, and 8 and in accordance with the methods disclosed by Fischell. Such an upwardly cutting configuration is clearly distinct from a cutting surface extending along a *bottom portion* of a needle. Fischell neither discloses nor suggests a **cutting surface** on a bottom surface of a needle having an opening on an upper surface of the same distal end.

In view of the above, independent claims 1, 8, 16, and 17, as amended, are patentable over Fischell. Claims 2-6, 9, 10, 11-15, 20, and 21, which depend from amended claims 1, 8, 16, and 17 respectively, are similarly patentable. Therefore,

withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C § 103

Claim 7 stands rejected under 35 U.S.C. § 103 as being obvious over Fischell. This rejection is respectfully traversed.

Claim 7 depends from amended independent claim 1 and is therefore patentable over Fischell for at least the same reasons discussed above with respect to amended claim 1. In particular, Fischell neither discloses nor suggests a sharpened cutting surface located on the bottom of the distal end of a hollow shaft having an opening at its upper distal end, as recited in claim 1. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 19 stands rejected under 35 U.S.C. § 103 as being obvious over Fischell in view of U.S. Patent No. 4,945,895, issued to Takai et al. ("Takai"). This rejection is respectfully traversed.

Claim 19 depends from amended independent claim 17 and is therefore patentable over Fischell for at least the same reasons discussed above with respect to amended claim 17. In particular, Fischell neither discloses nor suggests a sharpened cutting surface located along a bottom portion of the distal end of a hollow shaft having an opening at its upper distal end, as recited in claim 17. Takai also fails to disclose or suggest such a cutting surface and configuration as recited in claim 17. Therefore, claim 19 is patentable over Fischell and Takai. Accordingly, withdrawal of this rejection is respectfully requested.

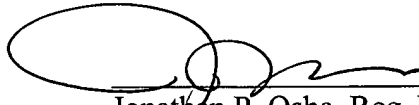
Conclusion

Applicants believe this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 06570.002002).

Respectfully submitted,

Date: _____

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